

REMARKS

Claims 1-5, 7-12, and 46-60 were pending. By virtue of this response, claims 7, 11, and 57 have been cancelled, and claims 1, 8-10, 46, 49, 55, 59, and 60 have been amended. Accordingly, claims 1-5, 8-10, 12, 46-56, and 58-60 are currently under consideration.

Support for the changes to claims 1, 46, 55, 59, and 60 is at 0042 and 0069. Claims 8-10 and 49 were amended to change dependencies and to reconcile them with the amendments to claims 1 and 46.

Turning to the Office Action, all claims were rejected under 35 U.S.C. § 103 as being unpatentable over several combinations of the following patents and publications: (1) U.S. Patent No. 6,955,657 to Webler, (2) U.S. Patent No. 6,656,182 to Hayhurst, (3) U.S. Patent No. 6,921,378 to O'Keefe, (4) U.S. Patent Application Pub. No. 2003/0167071 to Martin et al., and (5) U.S. Patent Application Pub. No. 2002/0087098 to Iwami et al. Applicants respectfully traverse these rejections.

First, several of the reasons stated in the Office Action as to why a proposed combination of features from the above patents and publications would have been obvious are not supportable, with the result that the Office Action fails to set forth a *prima facie* case as to why the claims are unpatentable for obviousness. See M.P.E.P. § 706.02(j); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (cited with approval in *KSR v. Teleflex*, 550 U.S. __, 127 S.Ct. 1727 (2007)). For example, claims 1, 2, 7-12, 55, and 57-60 were rejected over the combination of the Webler and Hayhurst patents. The Examiner contends that:

Hayhurst teaches that the device, including the anchor member positioned at said tip, solves the problem of manipulating and anchoring tissue when access to a tissue site is limited, therefore it would be obvious to one of ordinary skill in the art to modify the device of Webler so as to include an anchoring member that is placed within the tip of said needle 24 and is moveable out of the penetrating tip of said needle as taught by Hayhurst to facilitate manipulation and anchoring of tissue in sites where access is limited.

(Office Action, pg. 3). But the Webler device is not concerned with the objective of “facilitat[ing] manipulation and anchoring of tissue in sites where access is limited.” Instead, Webler’s device is designed and constructed to deliver substances (e.g., drugs) and/or to form holes in ischemic ventricular tissue to promote myocardial revascularization. (Webler, col. 1, lines 12-31). Thus, there is no reason why a person skilled in the art would place an anchor

member within the needle at the tip of the Webler device. In fact, doing so would defeat the purpose for having the needle in the Webler device in the first place, as the device would no longer be capable of delivering drugs.

As another example, claims 3-5, 48, and 56 were rejected over the combination of Webler and Hayhurst, in further view of the O'Keefe patent. The error in combining Webler and Hayhurst in the manner suggested by the Examiner is set forth above. That error is compounded by the addition of O'Keefe. The Examiner contends that:

O'Keefe teaches a drainage catheter having slots present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11). Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of Webler and Hayhurst so as to have a plurality of larger cut slots as taught by O'Keefe to aid liquid flow through the retention end of said tube.

(Office Action, pg. 8). But neither the Webler device nor the Hayhurst device is concerned with the objective of "aid[ing] liquid flow through the retention end of said tube." Thus, there is nothing gained by adding the drainage slots to either of the Webler or Hayhurst devices. Once again, there is simply no reason why a person skilled in the art would have combined these patents in the manner suggested.

As yet another example, claim 11 was rejected over the combination of Webler and Hayhurst, in further view of the Martin publication. The Examiner contends that:

Martin teaches that coil element 102 is a positioning device for sutures positioned therethrough and is slideable to a desired position along catheter 200. ('071, ¶¶ 0056, 0057). Martin also teaches that such sliding allows said coil element 102 to be advanced along a suture to a desired position for anchoring or fastening, therefore it would be obvious to one of ordinary skill in the art to modify the device of Webler and Hayhurst so as to have a coil translatable disposed within a tube lumen to aid or replace the suture anchor taught by Hayhurst and further allowing proper positioning and fastening of the sutures at a desired site as taught by Martin.

(Office Action, pp. 10-11). Once again, neither the Webler device nor the Hayhurst device is concerned with "positioning and fastening of the sutures at a desired site." The Office Action states no basis for why this proposed combination even makes sense, much less why it would have been obvious. Furthermore, to state that the Martin coil should be disposed

within a tube lumen to “replace the suture anchor taught by Hayhurst” is to remove the only reason the Hayhurst patent was included in the combination to begin with.

Finally, claims 46-53 were rejected over another combination of Hayhurst and Webler. The Examiner identified the shield 36 of the Hayhurst device as corresponding to the “tube” recited in Applicants’ claims, and granted that Hayhurst does not teach that the shield 36 is flexible. The Examiner therefore turned to Webler:

Webler teaches a needle 24 within a flexible tube 10. Webler teaches that the flexibility allows for easier placement of said needle catheter 20, therefore it would be obvious to one of ordinary skill in the art to modify the article of Hayhurst so as to replace the tube 36 with a flexible tube as taught by Webler to allow ease of access and placement of said needle and needle catheter.

(Office Action, pg. 11). This analysis ignores the fact that the Hayhurst shield 36 is only used to protect the anchor from the sharp tip of the needle during anchor loading. (Hayhurst, col. 5, line 61 to col. 6, line 3). Once the anchor is lodged in the needle, the shield 36 is removed. (Hayhurst, col. 6, lines 13-15). The shield 36 is not even present on the Hayhurst device during use. Making the shield 36 flexible, therefore, would not “allow ease of access and placement of said needle and needle catheter.” Once again, there is simply no reason why a person skilled in the art would have combined these patents in the manner suggested.

Based on the foregoing, the Office Action fails to establish a prima facie case that any of the claims are unpatentable for obviousness. Applicants respectfully request withdrawal of the rejections, and allowance of all of the pending claims.

In addition, in order to expedite prosecution and to facilitate allowance of claims to which Applicants are entitled, Applicants have amended each of the independent claims (claims 1, 46, 55, 59, and 60) to recite that the catheter has a flexible tube and has “a coil on a front end of a shaft that is translatable disposed within a lumen in said tube, said coil being extendible out of the front end of the tube.” These features further distinguish the claims from the cited patents and publications. For example, in the rejection of claim 7 in the pending Office Action, the Examiner stated that: “Webler teaches a coil 100 considered herein to be fixedly attached to a distal end of the tube 10.” Without acceding to the Examiner’s characterization of the Webler device, the Webler coil 100 certainly is not “on a front end of a shaft that is translatable disposed within a lumen in said tube,” nor is the Webler coil 100 “extendible out of the front end of the tube.” Furthermore, in the rejection

of claim 11 discussed above, the Examiner stated that: "Martin teaches that coil element 102 is a positioning device for sutures positioned therethrough and is slidale to a desired position along catheter 200." Once again, without acceding to the Examiner's characterization of the Martin device, the Martin fastening element 102 is also not "on a front end of a shaft that is translatable disposed within a lumen in said tube."

Accordingly, all of the independent claims (claims 1, 46, 55, 59, and 60) are not obvious over any combination of Webler, Hayhurst, and Martin. The dependent claims are patentable for the same reasons. For these additional reasons, Applicants respectfully request withdrawal of the rejections, and allowance of the claims.

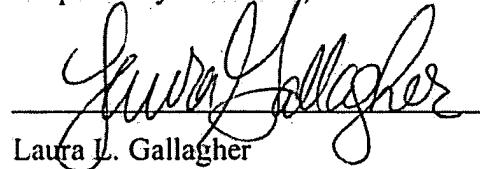
Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Similarly, unless explicitly stated, nothing contained or not contained in this paper should be construed as an assent to any of the Examiner's stated grounds for rejecting the claims, including specifically the Examiner's characterization of the teachings of the cited art and the Examiner's contentions that any combinations of cited art would have been obvious. Rather, the present amendments to the claims and Remarks are an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02110**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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